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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

ANITA LAUX,

Plaintiff,

v.

MENTOR WORLDWIDE, LLC; MENTOR CORPORATION; ETHICON, INC.; JOHNSON & JOHNSON and JOHN DOE DEFENDANTS # 1-10,

Defendants.

Case No. 2:16-cv-01026-ODW-AGR

Assigned to Honorable Otis D. Wright II

DEFENDANT MENTOR WORLDWIDE LLC'S NOTICE OF MOTION AND MOTION FOR SUMMARY JUDGMENT; MEMORANDUM OF POINTS AND AUTHORITIES

Date: September 11, 2017
Time: 2:30 p.m.
Ctrm.: 5D
Judge: Hon. Otis D. Wright II

Filed concurrently with Statement of Uncontroverted Facts; Declaration of Dustin B. Rawlin; and [Proposed] Judgment]

Pretrial Conference: September 18, 2017
Trial Date: September 26, 2017

TO PLAINTIFF ANITA LAUX:

PLEASE TAKE NOTICE that on September 11, 2017, 2:30 p.m., or as soon thereafter as the matter may be heard in Courtroom 5D of the above-referenced court, located at 350 W. 1st Street, Los Angeles, California, 90012, Defendant Mentor Worldwide LLC ("Mentor") will and does hereby move the Court for a judgment, pursuant to Federal Rules of Civil Procedure 56 and L.R. 56-1, entering summary judgment on all of Plaintiff's claims. This motion is made following the attempted conference of counsel pursuant to L.R. 7-3 which took place on February 17, 2017 with Plaintiff's former counsel and again with Plaintiff on July 31, 2017.

This Motion is based on the grounds that Plaintiff Anita Laux's claims are expressly preempted by the Medical Device amendments to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360k because the device at issue in this action, a Mentor Smooth Saline Breast Implant, is a Class III medical device that was evaluated and approved pursuant to the U.S. Food and Drug Administration's premarket approval (PMA) process. To the extent Plaintiff's claims are not preempted, this Motion is based on the grounds that Plaintiff failed to set forth sufficient evidence proving that the Mentor Saline Breast Implant was defectively and/or negligently manufactured, and that such defect caused her injuries. Further, Plaintiff failed to set forth any evidence showing she attempted to recover under Mentor's Limited Warranty or that Mentor breached such warranty.

The grounds for this Motion are this Notice and Motion, the attached Memorandum in Support of this Motion, the Statement of Uncontroverted Facts, the Declaration of Dustin B. Rawlin, the supporting exhibits attached, the pleadings, records, and files in this action, and such other evidence and argument as may be presented at or before the time of hearing.

DATED: August 4, 2017

TUCKER ELLIS LLP

By: */s/ Monee Takla Hanna*
Dustin B. Rawlin
Mollie F. Benedict
Monee Takla Hanna
Attorneys for Defendant
MENTOR WORLDWIDE LLC

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page

CASES

STATUTES

RULES

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

This is a products liability action concerning Mentor's Saline Breast Implants, which are "Class III" medical devices approved by the U.S. Food and Drug Administration ("FDA") through the premarket approval process after the device's design, manufacture, and labeling was approved, and the product was found to be safe and effective by the FDA. Plaintiff Anita Laux ("Plaintiff") has asserted three claims against Mentor Worldwide LLC ("Mentor") for injuries allegedly relating to her saline-filled breast implants: (1) strict liability manufacturing defect, (2) negligent manufacturing defect, and (3) breach of warranty. SUF ¶ 1. The undisputed facts confirm that all claims fail as a matter of law. Summary judgment is appropriate.

First, the U.S. Supreme Court's decision in *Reigel v. Medtronic*, 552 U.S. 312 (2008), requires summary judgment on Plaintiff's strict products liability and negligence claims in favor of Mentor. The Supreme Court in *Riegel* held that federal law bars individual state law personal injury claims challenging the safety and effectiveness of medical devices like Mentor's Saline Breast Implants. *Id.* at 322–25. Under *Riegel*, these state-law products liability claims, if successful, would impose design, manufacturing, or labeling requirements different from, or in addition to, those approved by the FDA as safe and effective and therefore are preempted by the Medical Device Amendments, 21 U.S.C. §§ 360 *et seq*., to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 *et seq*. Nor has Plaintiff alleged a viable state-law "parallel" claim that survives express preemption.

Second, to the extent Plaintiff's claims are not preempted, they also fail as a matter of law. Plaintiff's claims for manufacturing defect fail because they are premised on two unprovable assertions, *i.e.*, that the Mentor Saline Breast Implants at issue were defective and that the implants proximately caused Plaintiff's alleged injuries. Indeed, the undisputed facts confirm that pursuant to FDA good manufacturing practices, Mentor manufactured and sold implants that complied with the FDA-approved design. The

implants did not malfunction in any way, and Mentor was not negligent in any way. And, to the extent Plaintiff actually sustained any alleged injuries, she has proffered no reliable scientific or medical evidence whatsoever (nor could she) to connect those injuries to Mentor's implants. Thus, for these two fundamental reasons, Plaintiff's manufacturing defect claims fail as a matter of law.

Finally, Plaintiff's breach of warranty claim also fails. Plaintiff has failed to set forth any facts suggesting that she has complied with the conditions of the warranty. Nor has she alleged facts supporting an essential elements of her claim – that a breach of warranty occurred because she has never made a claim.

Thus, for these reasons, summary judgment should be granted and Plaintiff's claims should be dismissed.

II. FACTUAL BACKGROUND

On December 30, 2005, Plaintiff Anita Laux was surgically implanted with Mentor Smooth Round High Profile Saline Breast Implants. SUF ¶ 22. On May 23, 2014, Plaintiff underwent explant surgery to have her implants removed. SUF ¶ 25. Plaintiff alleges that she experienced various injuries, including debilitating bio-toxin disease, auto-immune disorders, respiratory, neurological, and immune diseases, fibromyalgia, fibrotic masses and fibrils (the start of silicosis, as silica from the breast implants was flaking into the wall of Plaintiff's chest), pain in the forearms and hands, pain in the right side of the body near the liver, difficulty breathing, pain in the middle of the chest, a cracking sound on the right side of the neck, vision and eye issues, severe vertigo, tinnitus, pain, severe fatigue and disfigurement. SUF ¶ 5.

The Mentor Saline Breast Implants are Class III medical devices as defined by 21 C.F.R. § 878.3530. The most stringent controls apply to Class III devices under the Medical Device Amendments, 21 U.S.C. §§ 360 *et seq.*, to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 *et seq*. *See Riegel*, 552 U.S. at 316. Because of its Class III status, the commercial sale of Mentor Saline Breast Implants to healthcare professionals was conditioned upon the device receiving premarket approval from the

FDA. *See* 21 C.F.R. § 878.3530(c).

Premarket approval ("PMA") is the process by which a manufacturer provides the FDA with a "reasonable assurance" that a Class III device is both safe and effective. *See* 21 U.S.C. § 360e(d)(2). Premarket approval is a "rigorous" process that requires a manufacturer to submit a PMA application containing specific information and data about the safety and efficacy of a Class III device which is then scrutinized by the FDA. *Riegel*, 552 U.S. at 317–18. This includes the design specifications, manufacturing processes, and labeling being proposed by a manufacturer. *Id*. The FDA grants PMA only if the agency has "reasonable assurance" that the device is safe and effective under the conditions of use included on the label. *See* 21 U.S.C. §§ 360e(d)(2); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996) Additionally, the agency approves the labeling of the product and is free to impose device-specific restrictions by regulation. 21 U.S.C. § 360j(e)(1).

If the Class III device is approved, the FDA issues an approval order. 21 C.F.R. § 814.44(d)(1). The approval order requires the manufacturer to adhere to the design, manufacture, and labeling specifications which the FDA approved as safe and effective as a result of the Class III device undergoing the premarket approval process. *See* 21 C.F.R. § 814.80. Following approval, "the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Riegel*, 552 U.S. at 319 (citing 21 U.S.C. § 360e(d)(6)(A)(i)). The FDA may also require post-approval studies as a condition of approval under 21 C.F.R. § 814.82(a)(2).

On November 12, 1999, Mentor submitted a PMA application for its Saline Breast Implants. SUF ¶ 6. During the FDA approval process, Dr. Pierre Blais presented testimony to the FDA Panel reviewing Mentor's PMA submission regarding his opinions of Mentor Saline Breast Implants and allegedly faulty valves. SUF ¶ 7. He testified as to the exact same opinions which he proffers in this case, *i.e.*, that Mentor's diaphragm valves on saline implants allow a bidirectional flow of bodily fluid into the implant and

saline out of the implant resulting in microbiological contamination of the implant. *Id*. Dr. Blais also submitted comments in writing to the Panel on the same topic. *Id*. Notwithstanding Dr. Blais's testimony, on May 10, 2000, the FDA found that the Mentor Saline Breast Implants as designed, manufactured and labeled are safe and effective, and the FDA issued an Approval Order. SUF ¶ 8. These approvals remain in effect and have never been suspended or revoked. SUF ¶ 8. Thereafter, Mentor Saline Breast Implants could only be sold to healthcare professionals in accordance with the design, manufacturing, and labeling specifications approved by the FDA. SUF ¶ 9; *see also* 21 C.F.R. § 801.109.

III. ARGUMENT[1]

A. FEDERAL LAW BARS PLAINTIFF'S CLAIMS.

1. The Medical Device Amendments to the Food, Drug and Cosmetic Act Preempt Additional or Different State Law Requirements Related to the Safety or Effectiveness of a Federally Approved Medical Device.

The Supremacy Clause of the United States Constitution states that the "Laws of the United States … shall be the supreme Law of the Land." U.S. Const., art. VI, cl. 2. Because federal law is supreme, any "state law that conflicts with federal law is 'without effect.'" *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992).

a. Medical Device Amendments of 1976

Congress gave the FDA exclusive regulatory authority over medical devices when

[1] The federal summary judgment standard is well established. Summary judgment must be granted when no genuine dispute as to any material fact exists and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). A party seeking summary judgment bears the initial burden of informing the court of the basis for its motion, and of identifying those portions of the pleadings, depositions, discovery responses, and affidavits that demonstrate the absence of a genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986). Material facts are those that might affect the outcome of the case. *Anderson v. Liberty Lobby, Inc*., 477 U.S. 242, 248, 106 S.Ct. 2504, 91 L.Ed.2d 202 (1986). The "mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no genuine issue of material fact." Id. at 247–48 (dispute as to a material fact is "genuine" if there is sufficient evidence for a reasonable jury to return a verdict for the nonmoving party).

it amended the Food, Drug and Cosmetic Act by enacting the Medical Device Amendments of 1976 ("MDA"). 21 U.S.C. §§ 301 *et seq*. By establishing a regulatory regime for the oversight of medical devices, the amendments were expected "to provide for the safety and effectiveness of medical devices intended for human use." *Lohr*, 518 U.S. at 474 (citing the preamble to the MDA, 90 Stat. 539) (internal quotations omitted). The MDA establishes three classes of medical devices based on the level of oversight required to ensure their safety: Class I, Class II, and Class III. *Riegel*, 552 U.S. at 316; 21 U.S.C. § 360c(a)(1). Of the three classes, a Class III device receives the most federal oversight, and requires premarket approval by the FDA. *Id*.; *see also Buckman Co. v. Plaintiffs' Legal Comm.,* 531 U.S. 341 (2000) (identifying Class III devices as "incur[ring] the FDA's strictest regulation"). Generally, a device receives a Class III assignment if it cannot be established that a less stringent classification would "provide reasonable assurance of safety and effectiveness, and the device is 'purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health,' or 'presents a potential unreasonable risk of illness or injury.'" *Riegel*, 552 U.S. at 316 (quoting 21 U.S.C. § 360c(a)(1)(C)(ii)). Premarket approval of a Class III device is a "rigorous process" that requires an applicant to submit "full reports of all studies and investigations relating to the device's safety or effectiveness; a 'full statement of the components, ingredients, and properties . . . '; a full description of the manufacturing methods and the facilities and controls used for the device's manufacturing; [and] examples of the proposed labeling." *Riegel*, 552 U.S. at 317–18.

The FDA spends an "average of 1,200 hours" on each premarket approval application. *Id.* (quoting *Lohr*, 518 U.S. at 477). In determining whether to grant premarket approval of a Class III device, the FDA must, among other things, "weigh[] any probable benefit to health from the use of [a] device against any probable risk of injury or illness from such use." 21 U.S.C. § 360c(a)(2)(C). The FDA will also "rely on the conditions of use included in the proposed labeling as the basis for determining

whether or not there is a reasonable assurance of [the device's] safety and effectiveness." 21 U.S.C. § 360e(d)(1)(A). The FDA may condition its grant of premarket approval upon certain requirements. 21 U.S.C. §§ 360e(d). Once premarket approval has been granted, "the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Riegel*, 552 U.S. at 319 (citing 21 U.S.C. § 360e(d)(6)(A)(i)). Moreover, approved devices are also subject to ongoing reporting requirements related to the device's health and safety. *Id.* A manufacturer must inform the FDA of studies and investigations of its devices, as well as incidents where the device caused or could have caused serious injury and the FDA retains the authority to withdraw approval based on this information. *Id.*

Importantly, to ensure FDA oversight is not controverted by state regulatory measures, the MDA contains an express preemption provision which states in relevant part: "[N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—[¶] (1) which is different from, or in addition to, any requirement applicable under this Act to the device, and [¶] (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." 21 U.S.C. § 360k(a).

b. Medical Device Preemption Under *Riegel*

In *Riegel*, the United States Supreme Court considered whether the MDA's preemption provision barred common law claims that challenged the safety and effectiveness of Class III medical devices which received approval through the PMA process. 552 U.S. at 320. At issue was a catheter marketed by Medtronic—a Class III device that had received premarket approval from the FDA. *Id.* The plaintiffs alleged the catheter was "designed, labeled, and manufactured in a manner that violated" state common law, and that these defects caused severe injuries. *Id.* They brought claims for "strict liability; breach of implied warranty; and negligence in the design, testing,

inspection, distribution, labeling, marketing, and sale of the catheter." *Id*.

The *Riegel* court unequivocally construed the MDA's express preemption provision to preempt the plaintiffs' state law claims against the PMA-approved catheter. In so doing, the court established a two-step inquiry for determining whether state law claims are preempted by the MDA. First, the court "must determine whether the Federal Government has established requirements applicable to" the medical device at issue. *Id.* at 321. Second, if there are applicable federal requirements, the court must then determine whether the "common-law claims are based upon [state] requirements with respect to the device that are 'different from, or in addition to' the federal ones, and that relate to safety and effectiveness." *Id*. at 322.

As to the first part of the inquiry, *Riegel* held that the FDA's premarket approval imposes federal requirements because it is granted "only after [the FDA] determines that a device offers a reasonable assurance of safety and effectiveness" and because "the FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application." *Id*. at 323. In reaching this conclusion, the *Riegel* court expressly distinguished its prior holding in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), where the court had held that substantial-equivalence review pursuant to 21 U.S.C. § 510(k) did not impose a device-specific federal "requirement." *Riegel*, 552 U.S. at 322. Given that substantial-equivalence review enables medical devices to be "marketed only so long as they remain substantial equivalents of the relevant pre-1976 devices," the court regarded the process as an exemption rather than a requirement. *Id*.; *Lohr*, at 493–94.

The *Riegel* court continued:

> Premarket approval, in contrast, imposes 'requirements' under the MDA as we interpreted it in *Lohr*. Unlike general labeling duties, premarket approval is specific to individual devices. And it is in no sense an exemption from federal safety review—it *is* federal safety review. Thus, the attributes that *Lohr* found lacking in § 510(k) review are present here. While § 510(k) is 'focused on equivalence, not safety,' premarket approval is

> focused on safety, not equivalence.... [T]he FDA may grant premarket approval only after it determines that a device offers a reasonable assurance of safety and effectiveness. And while the FDA does not 'require' that a device allowed to enter the market as a substantial equivalent 'take any particular form for any particular reason,' the FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness.

Riegel, 552 U.S. at 322–23 (internal citations omitted).

Riegel is consistent with federal authority construing the PMA process to impose a federal requirement for the purpose of preemption. *See Erickson v. Boston Scientific Corp.*, 846 F. Supp. 2d 1085, 1091 (C.D. Cal. Dec. 12, 2011) (recognizing that there is "no dispute" that federal requirements apply to the device at issue approved through the PMA process); *Walker v. Medtronic, Inc.*, 670 F.3d 569, 577 (4th Cir. 2011) ("[B]ecause [] Class III devices are required to undergo the premarket approval process, federal requirements exist with respect to [] Class III devices."); *Wolicki-Gables v. Arrow In'l, Inc.*, 634 F.3d 1296, 1301 (11th Cir. 2011) (holding that medical device's pre-market approval "imposes specific requirements on it that are sufficient to preempt a state law claim").

As to the second part of the preemption inquiry, *Riegel* found that common law tort duties impose "'requirement[s]' and would be pre-empted by federal requirements specific to a medical device." *Riegel*, 552 U.S. at 323–24. The Court reasoned that common law liability implies that the defendant had a legal duty and that "a liability award can be, indeed is designed to be, a potent method of governing conduct and controlling policy." *Id*. at 324. Rejecting the notion that a state-law "requirement" was limited to a state statute or regulation, the *Riegel* court reasoned that "[s]tate tort law that requires a manufacturer's [device] to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the

same effect." *Rhynes v. Stryker Corp.*, No. 10-5619, 2011 WL 5117168, at *4 (N.D. Cal. Oct. 27, 2011 (quoting *Riegel*, 522 U.S. at 325); *see also Nimtz v. Cepin*, No. 08cv1294, 2011 WL 831182, at *4 (S.D. Cal. Mar. 3, 2011) ("[S]tates are not permitted to indirectly regulate the safety and effectiveness of an FDA approved medical device through the tort system."); *Grant v. Corin*, No. 3:15-CV-169-CAB-BLM, 2016 WL 4447523, at *3 (S.D. Cal. Jan. 16, 2016) (concluding "California 'requirements' include common law duties").

In *Riegel*, the United States Supreme Court concluded that both elements of its two–step inquiry were satisfied. Approval of a Class III medical device through the PMA process necessarily established "federal requirements." *Riegel*, 552 U.S. at 321–23. Further, "reference to a State's 'requirements' includes its common-law duties." *Id*. at 324. The court thus ruled that plaintiffs' state tort law claims against the PMA-approved catheter were preempted by the express preemption provision of the MDA. *Id*.

Following *Riegel*, "courts across the country have applied Section 360k(a) broadly, preempting all manner of claims from strict products liability and negligence . . . to breach of warranty . . . to failure to warn and manufacturing-and-design-defect claims. . . to negligence per se." *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.* (*"Medtronic Leads"*), 592 F. Supp. 2d 1147, 1152 (D. Minn. Jan. 5, 2009) (collecting cases). Likewise, California courts and the Ninth Circuit routinely apply § 360k(a) to dismiss cases against PMA-approved Class III medical devices based on preemption. *See Dunbar v. Medtronic, Inc.*, No. CV 14-01529-RGK(AJWx), 2014 WL 3056026 (C.D. Cal. June 25, 2014) (dismissing strict liability and design defect claims as expressly preempted).[2]

[2] *See also Anderson v. Medtronic*, No. 14-cv-00615-BAS(RBB), 2015 WL 2115342 (S.D. Cal. May 6, 2015) (dismissing strict liability, negligence, and negligence per se claims as expressly preempted); *Kashani-Matts v. Medtronic*, No. SACV 13-01161, 2013 WL 6147032 (C.D. Cal. Nov. 22, 2013) (granting motion to dismiss all plaintiff's claims as preempted); *Simmons v. Boston Scientific Corp.*, No. CV 12-7962, 2013 WL 1207421 (C.D. Cal. Mar. 25, 2013) (dismissing strict liability manufacturing, design and failure to warn claims dismissed as preempted); *Erickson*, 2011 WL 7036060 (granting judgment on the pleadings against all claims involving several pacemakers approved through PMA and PMA-equivalent processes); *Rhynes*, 2011 WL 5117168 (granting motion to dismiss as to all claims involving hip implant based on preemption); *Norton v. Independence Tech., LLC,* No. 2:10-cv-03218, 2011 WL 3584491 (E.D. Cal. Aug. 15, 2011) (granting

2. The FDA Has Mandated Specific Requirements for the Manufacture of Mentor Saline Breast Implants.

The first step of the preemption inquiry is the determination as to "whether the Federal Government has established requirements applicable to" the medical device at issue—*i.e.* the Mentor Saline Breast Implant. *Riegel*, 552 U.S. at 321. The Mentor Saline Breast Implant at issue in this case is a Class III device. The implant was approved by the FDA through the PMA process on May 10, 2000. SUF ¶ 8. The Mentor Saline Breast Implant at issue has been manufactured and marketed pursuant to a valid and current PMA, and such approval has never been revoked, suspended, or withdrawn. *See Riegel*, 552 U.S. at 319–20 ("The FDA has the power to withdraw premarket approval based on newly reported data or existing information and must withdraw approval if it determines that a device is unsafe or ineffective under the conditions in its labeling.").

The FDA approved specifications relative to the design, manufacture and labeling of the Mentor Saline Breast Implant are the only standard of care applicable thereto. *Id*. at 325. Therefore, any state-law products liability claims attempting to impose design, manufacture, or labeling requirements different from, or in addition to, those approved as safe and effective by the FDA are preempted by the Medical Device Amendments, 21 U.S.C. §§ 360 *et seq*., to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 *et seq*.

3. Plaintiff's Strict Liability and Negligence Claims Conflict with the FDA Requirements for the Manufacturing of Mentor Saline Breast Implants and Are Therefore Preempted.

The second step of the preemption inquiry is the determination of whether

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motion for judgment on the pleadings on preemption grounds against all claims in case involving PMA motorized stair-climbing wheelchair); *Nimtz*, 2011 WL 831182 (granting motion to dismiss on preemption grounds against all claims involving pacemaker approved via PMA); *Cohen v. Guidant Corp.*, No. CV-05-8070-R, 2011 WL 637472 (C.D. Cal. Feb. 15, 2011) (granting motion to dismiss on preemption grounds for pacemaker approved through PMA-equivalent process); *McGuan v. Endovascular Techs., Inc.*, 182 Cal. App. 4th 974 (2010) (holding MDA preempted strict product liability, negligence, breach of express warranty, breach of implied warranty, and consumer protection claims).

Plaintiff's state law claims rely on any requirement of California law applicable to Mentor Saline Breast Implants "that is 'different from, or in addition to' federal requirements and that 'relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device.'" *Riegel*, 552 U.S. at 323 (quoting 21 U.S.C. § 360k(a)). The MDA expressly preempts any state law claim that would impose different or additional duties relating to any requirement imposed through the PMA process. *Id.* at 327–28; *Erickson,* 2011 WL 7036060, at *4. Like the plaintiffs in *Riegel*, by alleging state law tort claims, Plaintiff is, in effect, attempting to impose manufacturing requirements upon the Mentor Saline Breast Implant which conflict with, or add a greater burden to, the specific federal requirements imposed by the FDA when it was granted premarket approval.

Plaintiff's threadbare and conclusory claims against Mentor for strict liability manufacturing defect (Count 1) and negligent manufacturing defect (Count 2) challenge the safety and effectiveness of the PMA-approved Mentor Saline Breast Implants. *See* SUF ¶¶ 2–4. These claims are identical to those found to be preempted by *Riegel* and its progeny.

The first cause of action, which asserts strict liability for a manufacturing defect, is preempted under *Riegel*. Plaintiff maintains that the Mentor Saline Breast Implants "contained manufacturing defects when they left the Defendants' possession." SUF ¶ 2. Plaintiff does not allege that Mentor deviated from any *specific* manufacturing requirement imposed by the FDA through the PMA process, but instead relies on allegations that Mentor purportedly violated vague and generic Current Good Manufacturing Practices ("cGMPs"). SUF ¶ 3. As explained in Part III.A.4.a, such claims are unacceptably vague and insufficient to survive express preemption.

In the second cause of action for negligence, Plaintiff alleges that Mentor was "grossly negligent" because the Mentor Saline Breast Implants contained manufacturing defects. SUF ¶ 4. Plaintiff, in essence, challenges the FDA's findings concerning the safety of Mentor's Saline Breast Implants, and therefore seeks to impose requirements

that differ from federal regulations. Accordingly, Plaintiff's negligence claim is expressly preempted. *See Riegel*, 552 U.S. at 327–28.

The reasoning behind dismissal of Plaintiff's claims is in line with *Riegel* and its progeny. Each claim would require "judges and juries to second-guess the balancing of benefits and risk of a specific device to their intended patient population—the central role of the FDA. . .." *Horn v. Thoratec Corp.*, 376 F.3d 163, 178 (3d Cir. 2004) (quoting the FDA's Amicus Curiae Letter Brief at 25–26). *Riegel* explicitly held that state law tort claims, including causes of action for strict liability and negligence, impose requirements that are different from, or in addition to, the device-specific federal requirements, and are thus preempted. *Riegel,* 552 U.S. at 324; *see also Walker*, 670 F.3d at 580 ("A common law tort claim that presupposes a Class III device should have been designed in a manner other than that contemplated by its premarket approval is therefore expressly preempted by the MDA as interpreted by *Riegel*." (citing *Riegel*, 522 U.S. at 324–25)).

The same is true here. Mentor Saline Breast Implants received premarket approval by the FDA on March 10, 2000. SUF ¶ 8. Plaintiff's strict liability claim is devoid of any plausible allegations that the Mentor Saline Breast Implants at issue in this case were not manufactured in accordance with the specifications approved by the FDA through the PMA process. By contending that they were, nevertheless, defective, Plaintiff seeks to impose requirements regarding the manufacturing of the Mentor Saline Breast Implants that are different from, or in addition to, what the FDA approved. Plaintiff has therefore failed to allege facts sufficient "to state a claim to relief that is plausible on its face." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 547 (2007).

The undisputed evidence shows that the Mentor Saline Breast Implants were manufactured in accordance with the PMA requirements. SUF ¶¶ 10–21. Plaintiff has not set forth any evidence showing otherwise. Plaintiff's own expert admits he does not know how the implant deviated from Mentor's PMA specifications. SUF ¶ 58. In fact, Dr. Blais has testified – before the FDA and in litigation, including in this case – that the Mentor diaphragm value is defectively *designed* – the exact type of claim that is expressly

preempted by the MDA. SUF ¶¶ 64–66. Thus, Plaintiff's strict liability and negligence claims are expressly preempted. *See, e.g., Chao v. Smith & Nephew, Inc.*, No. 13-CV-0114-H (BLM), 2013 WL 6157587 (S.D. Cal. Oct. 22, 2013) (granting partial summary judgment on design defect claim as expressly preempted); *Morgan v. Medtronic, Inc.*, 172 F. Supp. 3d 959, 968 (S.D. Tex. 2016) (granting summary judgment for defendant because plaintiff's manufacturing defect claim was preempted where it "would require the [product] to be manufactured differently than the FDA authorized"); *Hesik v. Boston Sci. Corp.*, No. 1:12-cv-00014-JMC, 2014 WL 5644699, at *7 (D.S.C. Nov. 4, 2014) (granting summary judgment for defendant on the grounds that plaintiff's parallel claim for negligence was expressly preempted where plaintiff offered no "actual proof of a specific manufacturing deviation from the Defibrillator's specifications required by the PMA."); *Franklin v .Medtronic, Inc.*, No. 09-cv-02301-REB-KMT, 2010 WL 2543579, at *5 (D. Colo. May 12, 2010) (granting summary judgment for defendant on express preemption grounds because plaintiff's claims "require a finding that the 7273 Device was defectively manufactured or designed, despite Defendant's compliance with the manufacturing and design standards established by the FDA's PMA of the device.").

Consequently, Plaintiff's strict liability (Count 1) and negligent (Count 2) manufacturing defect claims fall squarely within the MDA's express preemption provision and in accordance with *Riegel* and its progeny, and summary judgment in favor of Defendant is appropriate.

4. Plaintiff Has Not Pled a Plausible Parallel Claim that Survives Express and Implied Preemption.

Even if Plaintiff's manufacturing defect claims escape express preemption—which they do not—they still fail to assert a viable parallel claim.

a. <u>Plaintiff Fails to Plead a Parallel Manufacturing Defect Claim.</u>

Plaintiff's manufacturing defect claim, which relies on vague and unspecified cGMPs, does not support a parallel claim that survives express preemption. "CGMPs are

guidelines that do not create a federal requirement, and a claim based on alleged failure to comply with the guidelines fails to plead violation of a federal requirement." *Pearsall v. Medtronics, Inc.*, 147 F. Supp. 3d 188, 198 (E.D.N.Y. 2015). A claim mandating "compliance with such 'vague' standards effectively imposes "different, or additional" requirements, and is preempted by § 306." *Ilarraza v. Medtronic, Inc.*, 677 F. Supp. 2d 582, 588 (E.D.N.Y. 2009); *Medtronic Leads*, 592 F. Supp. 2d at 1157–58 (noting that, since CGMPs are "simply too generic, standing alone, to serve as the basis for Plaintiff's manufacturing-defect claim[,]" to hold Medtronic liable for conduct, in "the absence of a specific requirement in the CGMPs . . . would impose requirements 'different from, or in addition to' those under federal law" (citations omitted)).

5. Plaintiff Has Not Proven a Causal Nexus Between the Alleged Violations and Her Injuries.

Plaintiff's attempt to plead a parallel claim also fails because she has not plausibly alleged that any purported violations of federal requirements caused her specific injury. To properly plead parallel claims that survive preemption, a plaintiff must allege (1) the violation of a specific federal requirement applicable to the device; (2) the violation of an identical state-law duty; and (3) that the predicate federal violation caused his or her injuries." *Millman v. Medtronic*, No. 14-cv-1465, 2015 WL 778779, at *4 n.2 (D.N.J. Feb. 24, 2015).

Here, Plaintiff fails to draw the necessary causal link between the alleged federal violations and her injuries. Specifically, Plaintiff has set forth no facts proving that the Mentor Saline Breast Implants were defective, and that such defect *caused* her injuries; "she merely alleges the conclusion of causation itself." *Frere v. Medtronic*, No. EDCV 15-02338-BRO(DTBx), 2016 WL 1533524, at *6 (C.D. Cal. Apr. 6, 2016). Indeed, Plaintiff's experts admit that the saline inside breast implants could be contaminated via other pathways independent of any defect. SUF ¶¶ 43, 67. Plaintiff relies on an inference of defect *and* an inference of causation to support her assertion that the implants were manufactured defectively. She has articulated no facts, however, to support her

conclusion that the valves of her implants were manufactured defectively.

6. Two Courts Considering Identical Claims and Numerous Other Courts Have Held That State Law Claims Related to Breast Implants Are Preempted

Two federal courts have considered the identical claims made here in the context of federal preemption, *i.e.*, that the valves on Mentor's saline implants were defective and allowed "autoinflation" and contamination by microbiological activity. *Alfred v. Mentor Corp.*, No. 05-483, 2007 WL 708631, at *2–*7 (W.D. Ky. Mar. 5, 2007) (granting Mentor's motion for summary judgment on preemption and other grounds in case involving saline breast implants); *Cottengim v. Mentor Corp.*, No. 05-161, 2007 WL 2782885, at *2–*5 (E.D. Ky. Sept. 24, 2007) (granting Mentor's motion for summary judgment on preemption in case involving saline breast implants). In each case, Dr. Blais attempted to give opinions identical to those in this case, and the exact same deficiencies in his methodologies and opinions that existed in those cases exist here. He has not tested the valves. SUF ¶ 60. He has not tested his autoinflation theory. SUF ¶ 62. He has not published his theory. SUF ¶ 63. He has not tested the saline in the implants or the material he claims is inside. SUF ¶¶ 72–74. He does not know what, if anything, is in Plaintiff's implants. SUF ¶¶ 75–76. Even his reports in those cases are substantially identical to his report in this case. SUF ¶ 68. In each case, the court granted Mentor's motion to exclude Dr. Blais's opinions under *Daubert*. *Alfred v. Mentor Corp.*, 479 F. Supp. 2d 670 (W.D. Ky. 2007); *Cottengim v. Mentor Corp.*, No. 05-161, 2007 WL 4553995, at *1–4 (E.D. Ky. Sept. 24, 2007). The Court then entered summary judgment for Mentor on preemption because Plaintiff had no reliable evidence of a manufacturing defect. The exact same result is warranted here.[3]

In addition, numerous other courts – both before and after *Riegel* – have for years held that state law claims related to PMA-approved breast implants are preempted. *See*,

[3] Mentor incorporates by reference its concurrently filed Motion to Exclude Testimony of Pierre Blais, Ph.D. and supporting Exhibits and Memorandum of Points and Authorities.

e.g., *Clore v. Mentor Worldwide LLC*, No. 17-cv-0003-CVE-TLW (N.D. Okla. Apr. 24, 2017) (dismissing product liability claims regarding saline breast implants as preempted) (order attached as Exhibit L to Rawlin Decl. ¶ 14); *Lindler v. Mentor Worldwide LLC*, No. 3:14-1982-MGL, 2014 WL 6390307 (D.S.C. Oct. 23, 2014) (dismissing product liability claims regarding silicone gel breast implants as preempted); *Malonzo v. Mentor Worldwide, LLC*, No. C 14-01144, 2014 WL 2212235 (N.D. Cal. May 28, 2014) (dismissing product liability claims regarding saline breast implants as preempted); *Ford v. Mentor Worldwide, LLC,* No. 2:13-cv-06317 (E.D. La. Dec. 17, 2013) (dismissing product liability claims regarding saline breast implants as preempted) (order attached as Exhibit M to Rawlin Decl. ¶ 15); *Harris v. Mentor Worldwide LLC*, No. 12-cv-916 (E.D. Cal. Aug. 21, 2012) (dismissing product liability claims regarding saline breast implants as preempted) (minute order attached as Exhibit N to Rawlin Decl. ¶ 16); *Couvillier v. Allergan Inc.*, No. 10-1383, 2011 WL 8879258, at *1–2 (W.D. La. Jan. 20, 2011) (dismissing product liability claims regarding silicone gel breast implants as preempted); *Williams v. Allergan USA, Inc.*, No. CV-09-1160, 2009 WL 3294873, at *2–3 (D. Ariz. Oct. 14, 2009) (granting summary judgment on preemption in case regarding silicone gel breast implant); *Dorsey v. Allergan, Inc.*, No. 08-0731, 2009 WL 703290, at *1–6 (M.D. Tenn. Mar. 11, 2009) (granting summary judgment on preemption in case regarding silicone gel breast implants); *Herbert v. Mentor*, No. 04-413, 2007 WL 2893387, at *3–4 (D.N.J. Sept. 28, 2007) (granting summary judgment on preemption in case regarding saline breast implants); *Haddock v. Mentor Tex.*, No. 03-cv-2311, 2005 WL 3542563, at *4 (N.D. Tex. Mar. 25, 2005) (granting summary judgment on preemption in case regarding saline breast implants).

B. PLAINTIFF CANNOT PROVE DEFECT OR CAUSATION

1. The Undisputed Facts Confirm that the Mentor Implants at Issue Were Not Defective.

If summary judgment is not granted for Defendant on Plaintiff's manufacturing defect claim on preemption, Plaintiff still cannot prevail because her claim is founded

upon proving that something was wrong with the Mentor implants, *i.e.*, that they were defective. SUF ¶¶ 2, 4. Plaintiff is unable to do so here.

A manufacturing defect is "one that differs from the manufacturer's intended result or from other ostensible identical units of the same line of products." *Barker v. Lull Eng'g Co.*, 20 Cal.3d 413, 429, 143 Cal.Rptr. 225, 573 P.2d 443 (Cal. 1979). A "manufacturing defect" theory posits that a "suitable design is in place, but that the manufacturing process has in some way deviated from that design." *In re Coordinated Latex*, 99 Cal.App.4th 594, 613, 121 Cal.Rptr.2d 301 (Ct. App. 2002). The allegations may not simply track the general elements of strict products liability without pertinent factual allegations. *Lucas v. City of Visalia*, 726 F. Supp. 2d 1149, 1154 (E.D. Cal. 2010). A plaintiff alleging a manufacturing defect "must identify/explain how the [product] either deviated from [defendant's] intended result/design or how the [product] deviated from other seemingly identical [product] models." *Id.* To prevail under a negligence theory, as opposed to strict liability in tort, the plaintiff must prove the additional element "that the defect in the product was due to negligence of the defendant." *Merrill v. Navegar, Inc.*, 26 Cal.4th 465, 479, 110 Cal. Rptr.2d 370 (2001) (affirming summary judgment for product manufacturer on negligence claim); *See also Mariscal v. Graco, Inc.*, 52 F. Supp. 3d 973 (N.D. Cal. 2014) (granting summary judgment in favor of manufacturer on negligence claim).

Here, the undisputed evidence confirms that Plaintiff's implants were manufactured properly. Mentor followed FDA good manufacturing practices and used reasonable care in the manufacturing process. SUF ¶¶ 13–21. The implants conformed to their design specifications and were rigorously tested and inspected. *Id*. There is no evidence to the contrary.

Courts in this jurisdiction and around the country routinely grant summary judgment for medical device manufacturers (including Mentor) on defect-based claims where – like here – a plaintiff proffers no evidence that a defect existed in the device at issue. *See, e.g., Carson v. Depuy Spine, Inc.*, No. CV 06-7430-VBF(PLAx), 2008 WL

7258800, at *2 (C.D. Cal. Sept. 17, 2008), *aff'd*, 365 Fed. App'x. 812, 814 (9th Cir. 2010) (granting summary judgment for manufacturer of spinal disk because plaintiff failed to present evidence of defect with the device). *See also Tucker v. Wright Medical Technology, Inc.* Case No. 11-cv-03086-YGR, 2013 WL 1149717, at *11 (N.D. Cal. Mar. 19, 2013) ("To state here that a manufacturing defect 'cannot be ruled out' is simply speculation based on an absence of facts"); *Taylor v. Danek Med., Inc.*, No. 9507232, 1998 WL 962062, at *7–8 (E.D. Pa. Dec. 29, 1998) (granting summary judgment for manufacturer of bone screw because plaintiff failed to submit proof of defect); *Barnett v. Mentor H/S, Inc.*, 133 F. Supp. 2d 507, 511–12 (N.D. Tex. 2001) (granting summary judgment for Mentor on several defect-based claims because the plaintiff had "not presented competent summary judgment evidence to controvert Mentor's evidence that the implants were not defective"), *aff'd*, 31 Fed. App'x. 156 (5th Cir. 2001); *Gebhardt v. Mentor Corp.*, 191 F.R.D. 180, 185 (D. Ariz. 1999) (granting summary judgment for Mentor because plaintiff failed to submit proof of defect), *aff'd*, 15 Fed. App'x. 540 (9th Cir. 2001).

2. Plaintiff's Manufacturing Defect Claim Fails Because there Is No Proof that There Was Any Defect in the Mentor Implants.

It is undisputed that prior to placing the implants into Plaintiff, Plaintiff's physician, Dr. Bunkis, thoroughly examined and leak-tested the implants and found that they were sterile and free from defects. SUF ¶ 23. It is also undisputed that, after the implant surgery, Dr. Bunkis saw Plaintiff on at least two occasions and Plaintiff reported that she was happy and had no complications or complaints about her implants. SUF ¶ 24. And it is undisputed that, after Dr. Kolb convinced Plaintiff to undergo explant surgery, when the implants were removed they were intact; they had not ruptured, leaked, deflated or malfunctioned. SUF ¶¶ 37, 55–56. The implants contained precisely the anticipated volume of saline based on weight. SUF ¶ 39, 57. Cultures from Plaintiff's breast tissue were negative for aerobic or anaerobic microbial growth. SUF ¶¶ 27–28. Pathology of Plaintiff's breast tissue was normal. SUF ¶ 29.

Mentor's uncontroverted affirmative evidence confirms that the implants were not defective. Specifically, the Mentor implants have an FDA-approved design that has been subjected to years of clinical studies and have been determined to be "safe and effective" after undergoing the FDA's most rigorous review-process: pre-market approval. SUF ¶ 8. The implants that Plaintiff received underwent exhaustive pre-shipment quality assurance and sterility testing and inspection pursuant to FDA good manufacturing practices and met all requirements and specifications. SUF ¶¶ 19–21. Plaintiff's own designated "valves expert" cannot provide any testimony regarding *how* the implants deviated from manufacturing specifications. SUF ¶ 58, 69–70. He did not compare Plaintiff's implants to their design specifications contained in the lot histories. SUF ¶ 61. He did not test Plaintiff's implants to see if they deviate from specification. SUF ¶ 59–60, 71. He admits he does not know if they deviate from specifications. SUF ¶ 58.

Under these undisputed facts, Plaintiff cannot show that the Mentor implants were defective. Without such proof, summary judgment on Plaintiff's manufacturing defect claim is appropriate.

3. Plaintiff Cannot Prove General or Specific Causation.

Plaintiff's manufacturing defect claims are also founded upon proving that the Mentor implant caused her injuries. SUF ¶ 1. But Plaintiff cannot prove this essential element of her claims, either.

Where, like here, a plaintiff alleges complicated medical injuries from exposure to a product, expert medical testimony to a reasonable degree of certainty is required to carry plaintiff's burden of proving causation. *Sanderson v. International Flavors and Fragrances, Inc.*, 950 F.Supp. 981, 984 (C.D. Cal. 1996) (citing *Jones v. Ortho Pharmaceutical Corp.*, 163 Cal.App.3d 396, 403, 209 Cal. Rptr. 456 (Ct. App. 1985) (Holding that probable causes in a medical tort case are beyond the experience of laymen and can only be explained through expert testimony).

Plaintiffs have to show both "general" and specific" causation. General causation is the capacity of a product to cause an identified injury. *In re Hanford Nuclear*

Litigation, 292 F.3d 1124, 1133 (9th Cir. 2002). Specific causation is proof that the product in question caused the injury of which the plaintiff complains. *Id. See also Jager v. Davol, Inc.*, No. EDCV 16-1424 JGB (KKx), 2016 WL 6157942, at *3 (C.D. Cal. Oct. 20, 2016); *Brookhouser v. State of California*, 10 Cal.App.4th 1665, 1677, 13 Cal.Rptr.2d 658 (Ct. App. 1992) ("It is axiomatic that a defendant cannot be held liable in tort for an injury that he or she did not cause."). Plaintiff cannot prove either here.

It's not entirely clear what injuries Plaintiff is claiming. Plaintiff is apparently proffering a heretofore unproven, speculative theory, that Ms. Laux is suffering from the effects of "toxic mold biotoxin," whatever that may mean. This novel assertion, concocted by Dr. Kolb – a self-proclaimed psychic and holistic healer – is untested, not peer reviewed, and not generally accepted.[4] Plaintiff also suggests that her injuries are caused by "degraded silica" (from the implant shell) within the breast tissue. Dr. Blais set forth this idea, but he is not a medical doctor with diagnosis capability, and he has not tested Plaintiff's breast tissue for silica. SUF ¶¶ 47–52.

Plaintiff's lack of any causation proof is coupled with affirmative uncontroverted evidence showing that there is no link between Plaintiff's alleged injuries and the Mentor implants. The Mentor implants were manufactured according to specifications and underwent pre-shipment quality assurance and sterility testing. SUF ¶¶ 17–18. Before implantation, Plaintiff's physician confirmed that the implants were sterile and lacked any defects or anomalies. SUF ¶ 23. And, when they were removed, the implants had not malfunctioned and did not appear to contain any foreign material. SUF ¶¶ 26, 38.

These undisputed facts are bolstered by testimony from Plaintiff's own expert, Dr. Kolb. She testifies that she believes Plaintiff's injuries were caused by toxic mold biotoxin.[5] She admits, however, that implants can become contaminated with mold without being defective. SUF ¶ 43. Dr. Blais agrees. SUF ¶ 67.

[4] Mentor incorporates by reference its concurrently filed Motion to Exclude the Opinions of Dr. Susan Kolb and supporting Exhibits and Memorandum of Points and Authorities.

[5] Plaintiff's expert, Pierre Blais, stated that he was not providing testimony on causation. SUF ¶ 81.

At bottom, Plaintiff has not shown support for any of the numerous underlying suppositions that would have to exist to prove their causation theory. First, Plaintiff has not demonstrated that there actually is mold inside the Mentor implants. SUF ¶¶ 30–31, 33–36, 40–41, 53–54, 74–77. Plaintiff has not demonstrated that any such mold is "toxic" or harmful. SUF ¶¶ 41, 44–46. Plaintiff has not demonstrated that any material in either implant was capable of producing, and actually did produce, biotoxins. SUF ¶ 32. Plaintiff has not proven that any biotoxins could leak out of the implant into Plaintiff's body. SUF ¶¶ 33, 77. Plaintiff has not shown that there was enough biotoxin to cause her injuries (dose). SUF ¶¶ 33, 76. And, perhaps most importantly, Plaintiff has not proffered evidence that biotoxins are capable of causing the type of symptoms Plaintiff alleges (general causation) or that biotoxins in fact caused Ms. Laux's injuries in this case (specific causation). SUF ¶¶ 44–46, 72–73, 78–80. *See McClain v. Metabolife Inter., Inc.*, 401 F.3d 1233 (11th Cir. 2005) (generally discussing proof of causation in toxic tort cases). And even if there was mold in Plaintiff's implants – and there is not – Plaintiff cannot show that it was due to Mentor's conduct. SUF ¶¶ 13–21, 42.

Given that Plaintiff has utterly no support for her causation theory and, indeed, that the undisputed facts confirm that it is unfounded, summary judgment for Mentor is appropriate.

4. This Case Is Identical to *Lakey v. Mentor* (N.D. Ga.) Where the Court Granted Summary Judgment for Mentor for Lack of Proof of Causation.

Mentor has previously won this identical case on causation. In *Lakey v. Mentor Corp.*, No. 1:05-cv-929, 2007 WL 4811929 (N.D. Ga. Mar. 30, 2007), the plaintiff made identical claims based on the work of Dr. Kolb and Pierre Blais who served as experts for the plaintiff. *Id.* at *1. Like here, the plaintiff claimed injuries as a result of mold biotoxin illness from her saline implants' saline being contaminated with mold through leaky valves. *Id.* at *1. Like here, neither Dr. Kolb nor Pierre Blais did any testing of the plaintiff, the implants or the saline to confirm the presence of mold.

The Court observed:

> Defendant argues that Plaintiffs have not proffered any evidence in support of their causation theory. Defendant contends, for instance, that Plaintiffs have not shown that (1) any material in the left implant was a biotoxin; (2) any biotoxins leaked into Mrs. Lakey's body; (3) there were enough biotoxins that leaked to cause her injuries; (4) biotoxins are capable of causing the type of injuries Mrs. Lakey allegedly suffered from; or (5) the biotoxins did in fact cause Mrs. Lakey's injuries. Defendant also contends that even if there were biotoxins in the left implant that did cause Mrs. Lakey's injuries, there is no evidence that the mold got there because of Defendant's actions.
>
> The Court agrees with Defendant and finds that Plaintiffs have not presented sufficient evidence to create a genuine issue of material fact as to whether the implants proximately caused Mrs. Lakey's injuries. The only evidence presented by Plaintiffs on the issue of causation is the testimony of Dr. Kolb, as Dr. Blais offered no opinion on causation.
>
> Dr. Kolb testified regarding the relationship between Mrs. Lakey's left implant and the biotoxin. According to her testimony, she performed a "visual contrast sensitivity test"[8] on Mrs. Lakey that showed that she "had exposure to some form of toxin."
>
> However, Dr. Kolb performed no scientific or medical testing to determine if there was mold in Mrs. Lakey's body or in her implants. She does not know what type of mold allegedly was in Mrs. Lakey's body or in her implants. She also does not know if the type of mold allegedly in Mrs. Lakey's body or implants produces a biotoxin, and she did not perform any scientific or medical testing to confirm the presence of biotoxins in Mrs. Lakey's body or implants. Notably, the only test Dr. Kolb did perform (other than the visual contrast sensitivity test described above) came back negative: she took two cultures of the tissue surrounding Mrs. Lakey's left breast that came back negative for aerobic and anaerobic microbial growth. Accordingly, Plaintiffs have not met their burden of presenting sufficient evidence to create a genuine issue of

> material fact as to whether the implants proximately caused Mrs. Lakey's injuries.

Id. at *4. So too here, and for the same exact reasons, Mentor is entitled to summary judgment in this case.

5. Plaintiff's Counsel Admitted Under Oath That Based on the Evidence He Could Not in Good Conscience Oppose Summary Judgment.

Plaintiff's former counsel admitted he could not oppose a summary judgment motion. In a sworn declaration in support of his motion to withdraw as counsel, Mr. Milstein stated under penalty of perjury that he could not "proceed with her lawsuit *or oppose summary judgment*." SUF ¶ 89. After months of discovery and depositions, and significant cost incurred by Mentor, Mr. Milstein could not, without risking further sanctions for frivolous conduct, oppose Mentor's anticipated summary judgment motion. Mr. Milstein's statement should be considered a binding admission against Plaintiff's interest. *Am. Title Ins. Co. v. Lacelaw Corp.*, 861 F.2d 224, 227 (9th Cir. 1988) ("[S]tatements of fact contained in a brief *may* be considered admissions of the party in the discretion of the court."); *Jackson v. City of Inglewood*, No. CV 07-05311 TJH (AJW), 2009 WL 699948 (C.D. Cal. Mar. 12, 2009) (treating as judicial admissions statements made in declaration filed under penalty of perjury as part of opposition to motion to dismiss); *Gaxiola v. City of Los Angeles*, No. CV 10-6632 AMH (FMO), 2011 WL 13152821 (C.D. Cal. Sept. 1, 2011) (treating as judicial admissions statements made in declaration filed under penalty of perjury as part of opposition to motion to dismiss); *Hill v. City of Torrance*, No. CV 13-27060-SVW (KES), 2016 WL 3679298 (C.D. Cal. June 9, 2016) (treating factual assertions in plaintiff's complaint as admissions against interest).

C. PLAINTIFF'S BREACH OF WARRANTY CLAIM FAILS.

To establish a cause of action for breach of express warranty under California law, a plaintiff must prove that the seller (1) made an affirmation of fact or promise or

provided a description of its goods; (2) the promise or description formed part of the basis of the bargain; (3) the express warranty was breached; and (4) the breach caused injury to the plaintiff. *See Asghari v. Volkswagen Group of Amer. Inc.*, 42 F. Supp. 3d 1306 (C.D. Cal. 2013).

Plaintiff has not, and cannot, prove that Mentor breached the limited warranty. According to Mentor's Customer Quality database, Plaintiff contacted Mentor twice in 2015 to make a warranty claim, but failed to satisfy the conditions of the Mentor Standard Limited Warranty. SUF ¶¶ 82–86. Her physician has not contacted Mentor to confirm the occurrence of a covered event. SUF ¶ 87. She has not returned or had her physician return the explanted device to Mentor's Product Evaluation Department. SUF ¶ 88. She has not signed a release. *Id*. Plaintiff has never attempted to satisfy the conditions precedent. *In re Toyota Motor Corp. Unintended Acceleration Mktg., Sales Pracs. & Prods. Liab. Litig.*, No. 8:10ML 02151 JVS (FMOx), 754 F. Supp. 2d 1145, 1179 (C.D. Cal. 2010) (stating that "Plaintiffs who neither sought repairs pursuant to the recalls nor sought repairs for SUA-related issues may not pursue a claim for breach of express warranty based on the written warranty"). Therefore, Mentor cannot have breached the warranty. *See Gertz v. Toyota Motor Corp.*, No. CV 10-1089 PSG (VBKx), 2011 WL 3681647 (C.D. Cal. Aug. 22, 2011) (holding that "an express warranty is not considered breached unless and until the defendant refuses or fails to repair") (in the automobile context); *Rose v. Chrysler Motors Corp.*, 212 Cal.App.2d 755, 763, 28 Cal.Rptr. 185 (1963) ("the seller's liability for a breach of a warranty does not attach until he has had an opportunity to remedy the defects, his failure or refusal to act, where such opportunity is afforded the seller, fixes his liability.").

Because Plaintiff has not set forth any facts proving a breach of express warranty occurred, an essential element of her cause of action, summary judgment should be granted for Mentor.

IV. CONCLUSION

Based on the above, Defendant Mentor Worldwide LLC respectfully requests that the Court enter a judgment granting Defendant's Motion for Summary Judgment.

DATED: August 4, 2017

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